

REMARKS

I. Status of the claims

In the Final Office Action dated October 20, 2006 (hereinafter “the Office Action”), the Examiner has objected to the status identifiers associated with the claims. Claims 1-46 are pending in this application, with claims 1, 44 and 45 being independent claims. Claims 9-11, 23, 29 and 44-46 are withdrawn as encompassing non elected species or inventions. Accordingly, the Examiner’s objection has been accommodated. Applicants respectfully request the rejoinder and consideration of the withdrawn claims upon the identification of allowable subject matter in generic and/or linking claims.

Claim 1 has been amended to more clearly define the presently claimed invention. Support for the amendment to claim 1 is found throughout the specification including, for example, paragraphs 12, 21 and 27, *inter alia*. In view of the foregoing amendments and the following remarks, Applicants respectfully believe that the present claims are in condition for allowance.

II. Rejection under 35 U.S.C. § 112, first paragraph

At pages 2-3 of the Office Action, the PTO has rejected claims 1-8, 12-22, 24-28 and 30-43 under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. Specifically, the Examiner asserts that:

The amendment reciting “wherein the composition comprises at least about 5% by water, based on the total weight of composition” is new matter.

Applicants respectfully traverse the rejection. Applicants apologize for erroneously directing the Examiner to paragraph 30. Rather, Applicants wish to direct the Examiner to paragraph 38, which recites:

The gelatin dosage forms of the present invention, which retain excess water, disperse and essentially melt upon administration. The amount of water retained by the gel formulation of the invention is at least the amount required to provide for redispersability of the nanoparticulate active agent particles upon administration. This equates to a water content of from about 5% to about 97%, from about 20% to about 95%, from about 30% to about 92%, from about 45% to about 90%, or

from about 65% to about 85%, based on the total weight of the composition.

Clearly, the phrase “a water content of from about 5% to about 97%....based on the total weight of the composition” from paragraph 38 provides complete written description support for the claimed element “wherein the composition comprises at least about 5% by water, based on the total weight of composition.” Accordingly, Applicants respectfully believe that the rejection is overcome.

III. Rejections Under 35 U.S.C. § 102

At pages 3-4 of the Office Action, the PTO has rejected claims 1-8, 12-22, 24-28 and 30-43 under 35 U.S.C. § 102(b) as allegedly being anticipated by WO 00/18374 to Swanson *et al.* (hereinafter “Swanson”). At page 5 of the Office Action, the PTO has also rejected claims 1-8, 12-22, 24-28 and 30-33 under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Patent No. 6,316,029 to Jain *et al.* (hereinafter “Jain”). The rejections based on both Swanson and Jain have been made in the previous Office Action and were maintained by the Examiner, who considered Applicants’ previous arguments unpersuasive. Applicants respectfully traverse these rejections as they may have been applied to the presently pending claims.

(a) The rejections in view of Swanson are overcome.

The presently claimed invention is drawn to pharmaceutical compositions which comprise at least about 5% water and which exhibit gelation sufficient to retain excess water in the solid or semi solid state. None of these elements are disclosed by Swanson.

However, the Examiner notes that Swanson discloses “soft gelatin capsules” and then states that “[s]uch capsules are understood to inherently include at least 5% water.” The Examiner’s argument rests upon an assertion of some inherent property, but does not provide any rationale or cite to any reference that teaches that soft gelatin capsules contain at least 5% water. In the previous Office Action, the Examiner had pointed to page 15, line 19 to page 16, line 4, and to Examples 1-17. Page 15, line 19 to page 16, line 4 makes no mention of any specific amount of water. Examples 1-17 do describe the use of water in the process of

making various compositions, but such water is removed by drying and none of the final, pharmaceutical compositions contain at least 5% water. Accordingly, Swanson does not disclose, explicitly *or* inherently, a composition containing at least 5% water.

Even if Swanson had disclosed such a composition, which it had not, Swanson had not disclosed a composition that exhibited gelation sufficient to retain excess water in the solid or semi solid state. Accordingly, Swanson also fails to teach an additional element of the claim. For at least these reasons, Swanson does not anticipate the presently claimed invention.

The Examiner then argues that Swanson's compositions will, at some point after administration, contain at least 5% water. However, Swanson does not disclose that the gel-forming substance exhibits gelation sufficient to retain excess water in a solid or semisolid state. Moreover, the composition of Swanson only contains at least 5% water after administration, while the present claims are drawn to pharmaceutical compositions (*i.e.* prior to administration). Accordingly, for at least these reasons, Applicants respectfully believe that the rejection over Swanson has been overcome and should be withdrawn.

(b) The rejections in view of Jain are overcome

The rejection in view of Jain has, in the Office Action, been asserted under 35 U.S.C. § 102(b), while the prior rejection in view of Jain was asserted under 35 U.S.C. § 102(a). In light of the priority date of the present application of September 11, 2002 (the filing date of provisional application No. 60/409,587) and the issue date of November 13, 2001 of Jain, Applicants respectfully believe that the Examiner intended to assert the rejection under 35 U.S.C. § 102(a). Applicants respectfully traverse the rejection as it may have been applied to the presently pending claims.

Claim 1 recites, in part:

at least one gel forming substance, which exhibits gelation
sufficient to retain excess water in a solid or semi-solid state,

wherein the pharmaceutical composition comprises at least
about 5% water, based on the total weight of the composition.

Jain does not disclose any of these elements, and hence cannot anticipate the presently pending claims.

The Examiner also argues that Jain discloses processes in which the components are blended and water at amounts greater than 5% are used, pointing specifically to Example 3. Applicants note that Example 3 describes spraying water onto ketoprofen *granules* and subsequent drying. Thus, Example 3 does not disclose a feature of the presently claimed pharmaceutical composition and hence does not anticipate the presently claimed invention.

For at least these reasons, withdrawal of this ground for rejection is respectfully requested.

CONCLUSION

In view of the foregoing amendments and remarks, Applicants respectfully believe that all rejections have been rendered moot, accommodated, or overcome. Applicants respectfully request that the Examiner reconsider and withdraw the present rejections, and allow the presently pending claims. As Applicants believe that the pending claims are in condition for allowance, Applicants also request that the Examiner rejoin and examine the withdrawn claims.

If it is believed that telephone communication can expedite the prosecution of this application, the Examiner is invited to contact the undersigned at the number below.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check or credit card payment form being in the wrong amount, unsigned, post-dated,

otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicants hereby petition for such extension under 37 C.F.R. §1.136 and authorize payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

Date Jan 8 2007
FOLEY & LARDNER LLP
Customer Number: 31049
Telephone: (202) 672-5538
Facsimile: (202) 672-5399

By Michele M. Simkin
Michele M. Simkin
Attorney for Applicants
Registration No. 34,717